CORPORATE INTEGRITY AGREEMENT

BETWEEN THE

OFFICE OF INSPECTOR GENERAL

OF THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

VNA PLUS, INC.

I. PREAMBLE

VNA Plus, Inc. ("VNA") hereby enters into this Corporate Integrity Agreement ("Agreement") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to ensure compliance with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))(hereinafter collectively referred to as the "Federal health care programs") by VNA and its subsidiaries, VNA employees, contractors, and agents.

For the purposes of this Agreement, contractor shall be defined as anyone who is directly or indirectly involved with VNA's business operations related to the Federal health care programs and/or the costs (e.g. the amount paid to a contractor; items or services rendered, ordered or prescribed by a contractor) of which are included in claims for reimbursement made to any Federal health care program. For the purposes of this Agreement, the ordering of equipment or supplies from VNA by a health care professional shall not render that individual a contractor. For purposes of this Agreement, VNA's provision of health care items or services to a Federal health care program beneficiary does not constitute a contract with that beneficiary.

VNA's compliance with the terms and conditions in this Agreement shall constitute an element of VNA's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this Agreement, VNA is entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

VNA is a wholly owned subsidiary of Health Midwest Ventures Group, Inc., which in turn is a wholly owned subsidiary of Health Midwest, Inc. Both Health

Midwest, Inc. and Health Midwest Ventures Group, Inc. hereby agree that they will do nothing in their capacity as related entities of VNA that will interfere with, or diminish, VNA's ability to discharge VNA's corporate integrity obligations under this Agreement.

II. TERM OF THE AGREEMENT

The period of the compliance obligations assumed by VNA under this Agreement shall be five (5) years from the effective date of this Agreement (unless otherwise agreed to in writing by the parties). The effective date of this Agreement shall be the date on which the last signatory executes this Agreement.

III. CORPORATE INTEGRITY OBLIGATIONS

VNA Plus shall establish or make the following integrity obligations permanent features of its Compliance Plan.

A. COMPLIANCE OFFICER

Within ninety (90) days after the effective date of this Agreement, VNA shall appoint an individual to serve as Compliance Officer. The Compliance Officer shall be responsible for developing or adopting and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this Agreement and with the requirements of the Federal health care programs.

The Compliance Officer shall be a member of senior management of VNA, shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or Board of Directors of VNA and shall have unrestricted access to the Board of Directors. Any changes in the appointment of the Compliance Officer (including voluntary or involuntary personnel changes) or the duties of this position must be reported to OIG within fifteen (15) days of the effective date of the action. All other matters affecting the Compliance Officer shall be reported in accordance with Section V below.

B. COMPLIANCE COMMITTEE

VNA shall appoint a Compliance Committee within ninety (90) days after the effective date of this Agreement. The Compliance Committee shall be responsible for, at a minimum, compliance with the integrity obligations in this Agreement. VNA shall ensure that the Compliance Committee is continuously composed of representatives of the multiple disciplines and segments of VNA's operations (e.g., senior executives of each major department, such as clinical, human resources, audit and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities. Any changes in the appointment of individuals or their authority must be reported to OIG within fifteen (15) days of the effective date of the action. All other matters affecting the Compliance Officer shall be reported in accordance with Section V below.

C. WRITTEN STANDARDS

1. Code of Conduct. Within ninety (90) days of the effective date of this Agreement, VNA shall develop a written Code of Conduct as part of its Compliance Plan and shall maintain it in effect for the duration of this Agreement. The Code of Conduct shall be distributed to all VNA employees and contractors within ninety (90) days of the effective date of this Agreement.

VNA shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of managers, supervisors, and all other employees. The Code of Conduct shall, at a minimum, set forth:

a. VNA's commitment to full compliance with all statutes, regulations, and guidance applicable to Federal health care programs, including its commitment to prepare and submit accurate reimbursement claims consistent with Federal health care program regulations and procedures or instructions otherwise communicated by the Health Care Financing

- Administration ("HCFA") (or other appropriate regulatory agencies) and/or its agents;
- b. VNA's requirement that all of its employees and contractors shall be expected to comply with all statutes, regulations, and guidance applicable to Federal health care programs and with VNA's own policies and procedures (including the requirements of this Agreement);
- c. the requirement that all of VNA's employees and contractors shall be expected to report suspected violations of any statute, regulation, or guidelines applicable to Federal health care programs or with VNA's own policies and procedures;
- d. the potential consequences to both VNA and to any VNA employee or contractor as a result of any failure to comply with Federal health care program requirements and with VNA's own policies and procedures, or any failure to report such non-compliance; and
- e. the right of all VNA employees and contractors to use the confidential disclosure program, as well as VNA's commitment to confidentiality and non-retaliation with respect to good faith disclosures.

Within ninety (90) days of the effective date of the Agreement, each VNA employee and contractor shall certify, in writing, that he or she has received, read, understands, and will abide by VNA's Code of Conduct. New VNA employees and contractors shall receive the Code of Conduct and shall complete the required certification within two (2) weeks after the commencement of their employment, or contract, or within ninety (90) days of the effective date of the Agreement, whichever is later.

VNA will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be distributed within thirty (30) days of initiating such a change. VNA employees and

contractors shall certify on an annual basis that they have received, read, understand and will abide by the Code of Conduct.

2. Policies and Procedures. Within ninety (90) days of the effective date of this Agreement, VNA shall develop and implement written Policies and Procedures regarding the operation of VNA's compliance program and its compliance with all Federal and state health care statutes, regulations, and guidance by the agency in charge of administering the program and/or its agents. At a minimum, the Policies and Procedures shall specifically address proper billing procedures.

The Policies and Procedures shall incorporate the following requirements:

- a. The requirement that VNA staff submit for billing to Federal health care programs services or items only if they are properly documented as being medically necessary for the patient's individual needs unless the submission is properly identified as being for the purpose of establishing that the service is not covered.
- b. The requirement that VNA staff review the services and items to be billed to Federal health care programs to determine they are properly documented as being medically necessary under the relevant program requirements unless the submission is properly identified as being for the purpose of establishing that the service is not covered.
- to submission for billing for services and items billed to Federal health care programs to determine that the claim form and certificate of medical necessity meet the relevant program requirements.
- d. The requirement that VNA staff submit services or items for billing to Federal health care programs only if they were

ordered by the treating physician or other authorized person, have been provided, are covered, and are properly documented as being reasonable and necessary given the clinical condition of the patient.

- e. The requirement that VNA staff review each patient file prior to submission for billing to Federal health care programs to ensure that it accurately indicates the location of where the service was actually provided.
- f. The requirement that VNA staff review each patient file prior to submission for billing to Federal health care programs to ensure that there were no improper alterations to documentation supporting the claim submitted (e.g., patient records, certificates of medical necessity).

In addition, the Policies and Procedures shall include disciplinary guidelines and methods for VNA employees and contractors to make disclosures or otherwise report on compliance issues to VNA management through the Confidential Disclosure Program required by section III.F. VNA shall assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. A summary of the Policies and Procedures will be provided to OIG in the Implementation Report. The Policies and Procedures will be available to OIG upon request.

Within ninety (90) days of the effective date of the Agreement, the relevant portions of the Policies and Procedures shall be distributed to all appropriate VNA employees and contractors. Compliance staff or supervisors should be available to explain any and all policies and procedures.

D. TRAINING AND EDUCATION

1. General Training. In addition to the training already provided by VNA, within ninety (90) days of the effective date of this

Agreement, VNA shall provide at least one (1) hour of training to each VNA employee. This general training shall explain VNA's:

- a. Corporate Integrity Agreement requirements;
- b. Compliance Program (including the Policies and Procedures as they pertain to general compliance issues); and
- c. Code of Conduct.

The training material shall be made available to the OIG upon request.

New VNA employees shall receive the general training described above within thirty (30) days of the beginning of their employment or within ninety (90) days after the effective date of this Agreement, whichever is later. Each year, every VNA employee shall receive such general training on an annual basis.

- 2. Specific Training. In addition to the training already provided by VNA, after the anniversary date of this CIA, each VNA employee who is involved directly or indirectly in the delivery of patient care and/or in the preparation or submission of claims for reimbursement for such care (including, but not limited to, coding and billing) for any Federal health care programs shall receive at least two (2) hours of training in addition to the general training required above. This training shall include a discussion of:
 - a. the accurate submission of each patient file to VNA's billing company for items and services, including durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS") provided to Federal health care program patients;
 - b. policies, procedures and other requirements applicable to the documentation of medical records for each patient file;

- c. the personal obligation of each individual involved in the billing process to ensure that each patient file is accurate and that the items and services, including DMEPOS, were medically necessary;
- d. applicable reimbursement rules and statutes;
- e. the legal sanctions for improper billings;
- f. examples of proper and improper billing practices;
- g. providing DMEPOS items or services without proper authorization;
- h. improper alterations to documentation (<u>e.g.</u>, patient records, CMNs);
- i. signing a form for a physician without the physician's authorization; and
- j. billing the Federal health care programs for levels of service in excess of the services actually rendered.

These training materials shall be made available to OIG upon request. Persons providing the training must be knowledgeable about the subject area.

Affected new VNA employees shall receive this training within thirty (30) days of the beginning of their employment or within ninety (90) days of the effective date of this Agreement, whichever is later. If a new VNA employee has any responsibility for the delivery of patient care, the preparation or submission of claims and/or the assignment of procedure codes prior to completing this specific training, a VNA employee who has completed the specific training shall review all of the untrained person's work regarding the preparation or submission of claims and/or the assignment of procedure codes the assignment of billing codes and what services or items qualify as medically necessary.

Every affected VNA employee shall receive specific training on an annual basis.

3. Certification. Upon completion of each training session, each VNA employee shall certify, in writing, that he or she has attended the required general and specific training. The certification shall specify the type of training received and the date received. The Compliance Officer shall retain the certifications, along with specific course materials. These shall be made available to OIG upon request.

E. REVIEW PROCEDURES

VNA shall retain an independent entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization"), to perform review procedures to assist VNA in assessing the adequacy of its billing and compliance practices pursuant to this Agreement. This shall be an annual requirement and shall cover a twelve (12) month period. The Independent Review Organization must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which VNA seeks reimbursement. The Independent Review Organization must be retained to conduct the audit of the first year within ninety (90) days of the effective date of this Agreement.

The Independent Review Organization will conduct two engagements. One will be an analysis of VNA's billing to the Federal health care programs to assist VNA and OIG in determining compliance with all applicable statutes, regulations, and directives/guidance ("billing engagement"). The second engagement will determine whether VNA is in compliance with this Agreement ("compliance engagement").

1. Billing Engagement. The billing engagement shall consist of a review of a statistically valid sample of claims submitted to the Federal health care programs that can be projected to the population of claims for the relevant period. The sample size shall be determined through the use of a probe sample. At a minimum, the full sample must be within a ninety (90) percent confidence level and a precision of twenty-five (25) percent. The probe sample must

contain at least thirty (30) sample units and cannot be used as part of the full sample. Both the probe sample and the sample must be selected through random numbers. VNA shall use OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," which is available through the Internet at "www.hhs.gov/progorg/oas/ratstat.html".

Each annual billing engagement analysis shall include the following components in its methodology:

- a. Billing Engagement Objective: A clear statement of the objective intended to be achieved by the billing engagement and the procedure or combination of procedures that will be applied to achieve the objective.
- b. Billing Engagement Population: Identify the population, which is the group about which information is needed.
 Explain the methodology used to develop the population and provide the basis for this determination.
- c. Sources of Data: Provide a full description of the source of the information upon which the billing engagement conclusions will be based, including the legal or other standards applied, documents relied upon, payment data, and/or any contractual obligations.
- d. Sampling Unit: Define the sampling unit, which is any of the designated elements that comprise the population of interest.
- e. Sampling Frame: Identify the sampling frame, which is the totality of the sampling units from which the sample will be selected.

The billing engagement shall provide:

a. findings regarding VNA's billing and coding operation (including, but not limited to, the operation of the billing

- system, strengths and weaknesses of this system, internal controls, effectiveness of the system);
- b. findings regarding whether VNA is submitting accurate claims for items and services, including DMEPOS, billed to the Federal health care programs;
- c. findings regarding VNA's procedures to correct inaccurate billings or codings to the Federal health care programs;
- d. findings regarding whether VNA's programs, policies, operations, and procedures comply with the applicable statutes, regulations and other requirements the Federal health care programs from which VNA seeks reimbursement;
- e. findings regarding VNA's submitted claims in order to determine whether each patient file discloses they are for medically necessary services;
- f. findings regarding whether VNA is accurately completing certificates of medical necessity; and
- g. findings regarding the steps VNA is taking to bring its operations into compliance or to correct problems identified by the audit.
- 2. Compliance Engagement. An Independent Review Organization shall also conduct a compliance engagement, that shall provide an analysis of whether VNA's program, policies, procedures, and operations comply with the terms of this Agreement. This engagement shall include a section by section analysis of the requirements of this Agreement.

A complete copy of the Independent Review Organization's billing and compliance engagement shall be included in each of VNA's Annual Reports to OIG.

- 3. Disclosure of Overpayments and Material Deficiencies. If, VNA or the Independent Review Organization identifies any billing, coding or other policies, procedures and/or practices that result in a material deficiency or overpayment, VNA shall notify the appropriate government payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of discovering the deficiency or overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the deficiency from recurring. The notice to the payor shall include:
- a. a statement that the refund is being made pursuant to this Agreement;
- b. a description of the complete circumstances surrounding the overpayment;
- c. the methodology by which the overpayment was determined;
- d. the amount of the overpayment;
- e. any claim-specific information used to determine the overpayment (e.g., beneficiary health insurance number, claim number, service date, and payment date); and
- f. the provider identification number under which the repayment is being made.

If VNA determines an overpayment represents a material deficiency, contemporaneous with VNA's notification to the payor as provided above, VNA shall also notify OIG of:

- a. a complete description of the material deficiency;
- b. amount of overpayment due to the material deficiency;

- c. VNA's action(s) to correct and prevent such material deficiency from recurring;
- d. the payor's name, address, and contact person where the overpayment was sent;
- e. the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid.

For purposes of this Agreement, an "overpayment" shall mean the amount of money VNA has received in excess of the amount due and payable under the Federal health care programs statutes, regulations or program directives, including carrier and intermediary instructions.

For purposes of this Agreement, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment or improper payment relating to the Federal health care programs; (ii) conduct or policies that clearly violate the Federal health care program statutes, regulations or directives issued by HCFA and/or its agents; or (iii) serious quality of care implications for Federal health care beneficiaries. A material deficiency may be the result of an isolated event or a series of occurrences.

4. Verification/Validation. In the event that the OIG determines that it is necessary to conduct an independent review to determine whether or the extent to which VNA is complying with its obligations under this Agreement, VNA agrees to pay for the reasonable cost of any such review or engagement by the OIG or any of its designated agents.

F. CONFIDENTIAL DISCLOSURE PROGRAM

Within ninety (90) days after the effective date of this Agreement, VNA shall establish a Confidential Disclosure Program, which must include measures (e.g., a toll-free compliance telephone line) to enable VNA employees, contractors, agents or other individuals to disclose, to the Compliance Officer or some other person who is not in the reporting individual's chain of command, any identified issues or questions associated with VNA's policies, practices or procedures with respect to

Federal health care program, believed by the individual to be inappropriate. VNA shall publicize the existence of the hotline (<u>e.g.</u>, e-mail to VNA employees or post hotline number in prominent common areas).

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Upon receipt of a complaint, the Compliance Officer (or designee) shall gather the information in such a way as to elicit all relevant information from the individual reporting the alleged misconduct. The Compliance Officer (or designee) shall make a preliminary good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice, and (2) provides an opportunity for taking corrective action, VNA shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer shall maintain a confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation. A copy of this confidential disclosure log shall be submitted to the OIG in accordance with section V.B.8 of this Agreement.

G. INELIGIBLE PERSONS

1. Definition

For purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

2. Screening Requirements

VNA shall not hire or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, VNA shall screen all prospective employees and prospective contractors prior to engaging their services by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.arnet.gov/epls) and the OIG List of Excluded Individuals/Entities (available through the Internet at http://www.dhhs.gov/progorg/oig) (these lists and reports will hereinafter be referred to as the "Exclusion Lists").

3. Review and Removal Requirement

Within ninety (90) days of the effective date of this Agreement, VNA will review its list of current employees and contractors against the Exclusion Lists. Thereafter, VNA will review the list once semi-annually. If VNA has notice that an employee, agent, or physician has become an Ineligible Person, VNA will remove such person from responsibility for, or involvement with, VNA's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. Pending Charges and Proposed Exclusions

If VNA has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is suspended or proposed for exclusion during his or her employment or contract with VNA, within ten (10) days of receiving such notice VNA will remove such individual from responsibility for, or involvement with, VNA's business operations related to the Federal health care programs until the resolution of such criminal action, suspension, or proposed exclusion.

H. NOTIFICATION OF PROCEEDINGS

Within thirty (30) days of discovery, VNA shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that VNA or its divisions and subsidiaries has or have committed a crime or has or have engaged in fraudulent activities or any other knowing misconduct. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. VNA shall also provide written notice to OIG within thirty (30) days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

I. REPORTING

- 1. Credible evidence of misconduct. If VNA discovers credible evidence of misconduct from any source and, after reasonable inquiry, has reason to believe that the misconduct may violate criminal, civil, or administrative law concerning VNA's practices relating to the Federal health care programs, then VNA shall promptly report the probable violation of law to OIG. VNA shall make this disclosure as soon as practicable, but, not later than thirty (30) days after becoming aware of the existence of the probable violation. VNA's report to OIG shall include:
 - a. the findings concerning the probable violation, including the nature and extent of the probable violation;
 - b. VNA's actions to correct such probable violation; and
 - c. any further steps it plans to take to address such probable violation and prevent it from recurring.

To the extent the misconduct involves an overpayment, the report shall include the information listed in section III.E.3 regarding material deficiencies. 2. Inappropriate Billing. If VNA discovers inappropriate or incorrect billing through means other than the Independent Review Organization's engagement, VNA shall follow procedures in section III.E.3 regarding overpayments and material deficiencies.

IV. NEW LOCATIONS

In the event that VNA, its subsidiaries or divisions purchase(s) or establish(es) new business units after the effective date of this Agreement, VNA shall notify OIG of this fact within thirty (30) days of the date of purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program provider number(s) (if any), and the corresponding payor(s) (contractor specific) that has issued each provider number. All VNA employees and contractors at such locations shall be subject to the requirements in this Agreement that apply to new VNA employees and contractors (e.g., completing certifications).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. <u>IMPLEMENTATION REPORT</u>

Within one hundred and twenty (120) days after the effective date of this Agreement, VNA shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Agreement. This Implementation Report shall include:

- 1. the names, addresses, phone numbers and position description of the Compliance Officer required by section III.A;
- 2. the names and positions of the members of the Compliance Committee required by section III.B;
- 3. a copy of VNA's Code of Conduct required by section III.C.1;
- 4. the summary of the Policies and Procedures required by section III.C.2;

- 5. a description of the training programs required by section III.D including a description of the targeted audiences and a schedule of when the training sessions were held;
- 6. a certification by the Compliance Officer that:
 - a. the Policies and Procedures required by section III.C.2 have been developed, are being implemented, and have been distributed to all pertinent VNA employees and contractors;
 - b. all VNA employees and contractors have completed the Code of Conduct certification required by section III.C.1; and
 - c. all VNA employees have completed the training and executed the certification required by section III.D.
- 7. a description of the confidential disclosure program required by section III.F;
- 8. the identity of the Independent Review Organization(s) and the proposed start and completion date of the first audit; and
- 9. a summary of personnel actions taken pursuant to section III.G.

B. ANNUAL REPORTS

VNA shall submit to OIG an Annual Report with respect to the status and findings of VNA's compliance activities.

The Annual Reports shall include:

- 1. any change in the identity or position description of the Compliance Officer and/or members of the Compliance Committee described in sections III.A and III.B;
- 2. a certification by the Compliance Officer that:

- a. all VNA employees and contractors have completed the annual Code of Conduct certification required by section III.C.1;
- b. all VNA employees have completed the training and executed the certification required by section III.D;
- 3. notification of any changes or amendments to the Policies and Procedures required by section III.C.2 and the reasons for such changes (e.g., change in contractor policy);
- 4. a complete copy of the report prepared pursuant to the Independent Review Organization's billing and compliance engagement, including a copy of the methodology used;
- 5. VNA's response/corrective action plan to any issues raised by the Independent Review Organization;
- a summary of material deficiencies identified and reported throughout the course of the previous twelve (12) months pursuant to sections III.E.3 and III.I;
- 7. a report of the aggregate overpayments that have been returned to the Federal health care programs that were discovered as a direct or indirect result of implementing this Agreement. Overpayment amounts should be broken down into the following categories:

 Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;
- 8. a copy of the confidential disclosure log required by section III.F;
- 9. a description of any personnel action (other than hiring) taken by VNA as a result of the obligations in section III.G;
- 10. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that VNA has committed a crime or has engaged in

fraudulent activities, which have been reported pursuant to section III.H. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information;

- 11. a corrective action plan to address the probable violations of law identified in section III.I; and
- a listing of all of VNA's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s) and the payor (specific contractor) that issued each provider identification number.

The first Annual Report shall be received by the OIG no later than one year and sixty (60) days after the effective date of this Agreement. Subsequent Annual Reports shall be submitted no later than the anniversary date of the due date of the first Annual Report.

C. <u>CERTIFICATIONS</u>

The Implementation Report and Annual Reports shall include a certification by the Compliance Officer under penalty of perjury, that: (1) VNA is in compliance with all of the requirements of this Agreement, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the effective date of this Agreement, all notifications and reports required under this Agreement shall be submitted to the entities listed below:

OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

<u>VNA</u>:

Lisa Hoebelheinrich, Esq. - Compliance Officer VNA Plus, Inc.
2300 Meyer Blvd. Suite 123
Kansas City, MO 64132
Phone 816.276.9510
Fax 816.276.9166

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine, VNA's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (a) VNA's compliance with the terms of this Agreement; and (b) VNA's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by VNA to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of VNA's employees, contractors or agents who consent to be interviewed at their place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee, contractor or agent and OIG. VNA agrees to assist OIG in contacting and arranging interviews with such employees, contractors or agents upon OIG's request. VNA's employees may elect to be interviewed with or without a representative of VNA present.

VIII. DOCUMENT AND RECORD RETENTION

VNA shall maintain for inspection documents and records relating to reimbursement from the Federal health care programs for a period of six (6) years following the execution of this Agreement (or longer if otherwise required by law).

IX. Breach and Default Provisions

VNA is expected to fully and timely comply with all of the obligations herein throughout the term of this Agreement or other time frames herein agreed to.

A. STIPULATED PENALTIES FOR FAILURE TO COMPLY WITH CERTAIN OBLIGATIONS

As a contractual remedy, VNA and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

- 1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning ninety (90) days after the effective date of this Agreement and concluding at the end of the term of this Agreement, VNA fails to have in place any of the following:
 - a. a Compliance Officer;
 - b. a Compliance Committee;
 - c. written Code of Conduct;
 - d. written Policies and Procedures;
 - e. a training program; and
 - f. a Confidential Disclosure Program;

- 2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day VNA fails meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.
- 3. A stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day VNA:
 - a. hires or enters into a contract with an Ineligible Person after that person has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Federal health care programs (this Stipulated Penalty shall not be demanded for any time period during which VNA can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.G) as to the status of the person);
 - b. employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, VNA's business operations related to the Federal health care programs or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (this Stipulated Penalty shall not be demanded for any time period during which VNA can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.G) as to the status of the person); or
 - c. employs or contracts with a person who: (i) has been charged with a criminal offense related to any Federal health care program, or (ii) is suspended or proposed for exclusion, and that person has responsibility for, or involvement with, VNA's business operations related to the Federal health care programs (this Stipulated Penalty shall not be demanded for any time period before 10 days after VNA received notice of the relevant matter or after the resolution of the matter).

- 4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date that VNA fails to grant access) for each day VNA fails to grant access to the information or documentation as required in section VII of this Agreement.
- 5. A Stipulated Penalty of \$1,000 (which shall begin to accrue ten (10) days after the date that OIG provides notice to VNA of the failure to comply) for each day VNA fails to comply fully and adequately with any obligation of this Agreement. In its notice to VNA, the OIG shall state the specific grounds for its determination that VNA has failed to comply fully and adequately with the Agreement obligation(s) at issue.

B. PAYMENT OF STIPULATED PENALTIES

1. Demand Letter. Upon a finding that VNA has failed to comply with any of the obligations described in section IX.A and determining that Stipulated Penalties are appropriate, OIG shall notify VNA by personal service or certified mail of (a) VNA's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

Within fifteen (15) days of the date of the Demand Letter, VNA shall either (a) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section IX.D. In the event VNA elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until VNA cures, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this Agreement and shall be grounds for exclusion under section IX.C.

- 2. Timely Written Requests for Extensions. VNA may submit a timely written request for an extension of time to perform any act or file any notification or report required by this Agreement. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after VNA fails to meet the revised deadline as agreed to by the OIG-approved extension. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two (2) business days after VNA receives OIG's written denial of such request. A "timely written request" is defined as a request in writing received by OIG at least five (5) business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.
- 3. Form of Payment. Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI.
- 4. Independence from Material Breach Determination. Except as otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's determination that VNA has materially breached this Agreement, which decision shall be made at the OIG's discretion and governed by the provisions in section IX.C, below.

C. EXCLUSION FOR MATERIAL BREACH OF THIS AGREEMENT

1. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this Agreement by VNA constitutes an independent basis for VNA's exclusion from participation in the Federal health care programs. Upon a determination by OIG that VNA has materially breached this Agreement and that exclusion should be imposed, the OIG shall notify VNA by certified mail of (a)

VNA's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude Letter").

- 2. Opportunity to Cure. VNA shall have thirty five (35) days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:
 - a. VNA is in full compliance with this Agreement;
 - b. the alleged material breach has been cured; or
 - c. the alleged material breach cannot be cured within the 35-day period, but that: (i) VNA has begun to take action to cure the material breach, (ii) VNA is pursuing such action with due diligence, and (iii) VNA has provided to OIG a reasonable timetable for curing the material breach.
- 3. Exclusion Letter. If at the conclusion of the thirty five (35) day period, VNA fails to satisfy the requirements of section IX.C.2, OIG may exclude VNA from participation in the Federal health care programs. OIG will notify VNA in writing of its determination to exclude VNA (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section IX.D, below, the exclusion shall go into effect thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and federal non-procurement programs. If VNA is excluded under the provisions of this Agreement, VNA may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.
- 4. Material Breach. A material breach of this Agreement means:
 - a. a failure by VNA to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.E;

- b. repeated or flagrant violations of the obligations under this Agreement, including, but not limited to, the obligations addressed in section IX.A of this Agreement;
- c. a failure to respond to a Demand letter concerning the payment of Stipulated Penalties in accordance with section IX.B above; or
- d. a failure to retain and use an Independent Review
 Organization for review purposes in accordance with section
 III.E.

D. <u>Dispute Resolution</u>

- Review Rights. Upon the OIG's delivery to VNA of its Demand 1. Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this Agreement, VNA shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this Agreement. Specifically, the OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving stipulated penalties shall be made within fifteen (15) days of the date of the Demand Letter and the request for a hearing involving exclusion shall be made within thirty (30) days of the date of the Exclusion Letter.
- 2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for stipulated penalties under this Agreement shall be (a) whether VNA was in full and timely compliance with the obligations of this Agreement for which the OIG demands payment; and (b) the period of noncompliance.

VNA shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for the OIG with regard to a finding of a breach of this Agreement and orders VNA to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that VNA may request review of the ALJ decision by the DAB.

3. Exclusion Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this Agreement shall be (a) whether VNA was in material breach of this Agreement; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) whether the alleged material breach could not have been cured within the 35 day period, but that (i) VNA had begun to take action to cure the material breach within that period, (ii) VNA has pursued and is pursuing such action with due diligence, and (iii) VNA provided to OIG within the 35-day period a reasonable timetable for curing the material breach. For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to the OIG. VNA's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude VNA upon the issuance of the ALJ's decision. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that VNA may request review of the ALJ decision by the DAB.

X. <u>DISCLOSURES</u>

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify VNA prior to any release by OIG of information submitted by VNA pursuant to its obligations under this CIA and identified upon submission by VNA as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. VNA shall refrain from identifying any information as trade secrets,

commercial or financial information and privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA.

XI. <u>Effective and Binding Agreement</u>

Consistent with the provisions in the Settlement Agreement pursuant to which this Agreement is entered, and into which this Agreement is incorporated, VNA and OIG agree as follows:

- A. This Agreement shall be binding on the successors, assigns and transferees of VNA;
- B. This Agreement shall become final and binding on the date the final signature is obtained on the Agreement;
- C. Any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement; and
- D. The undersigned VNA, Health Midwest, Inc. and Health Midwest Ventures Group, Inc. signatories represent and warrant that they are authorized to execute this Agreement. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

ON BEHALF OF VNA PLUS, INC.

Liste D. Thewor	_	May 25/14
Richard Roberson	•	DATE
Chief Executive Officer of VNA Plus, Inc.		
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Approved as to form and content:		·
Jan a Jan		17-1 24, 1999
Lawrence A. Rouse, Esq.		DATE
Counsel for VNA Plus, Inc.		
Lacrow W. Brun		-1,-100
	•	3/25/4/
Richard Brown	•	DATE
Health Midwest, Inc. and	•	
Health Midwest Ventures Group, Inc.		
	•	
Approved as to form and content:		
a C Vin		May 24 1989
Larry A. Rouse, Esq.	,	DATE
Counsel for Health Midwest, Inc. and		
Health Midwest Ventures Group, Inc.	,	
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ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Lewis Morris

Assistant Inspector General for Legal Affairs

Office of Inspector General

U.S. Department of Health and Human Services

S/27
DATE